

2724-488

01/22/2013

1/5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 22 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

James McFadden
Sr. Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

Subject: RF 9804 Topical
EPA Registration No. 2724-488
Fast Track Amendment
Decision # 463800

Dear Mr. McFadden:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is **acceptable** provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit three (3) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at: adams.menyon@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda A. Hollis".

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

() Alternate Copy

RF 9804 TOPICAL

Alternate brand name: ZODIAC® Spot On® Flea Control for Cats & Kittens

Include "Cat" in product brand name and font size must be 75% of the size of the largest letter in the brand name

For use only on cats and kittens over 2.5 lbs & older than 12 weeks of age (front panel)

(Special formula)(for cats)(Specially formulated for cats)

Flea egg treatment

(Kills flea eggs), the source of flea infestations

(3)(4) month (90 or 120 day) supply, 1st dose, 2nd dose, 3rd dose, 4th dose

(3 or 4 months)(90 or 120 days) protection – (First month, Second month, Third month, Fourth Month, Month [1/2/3/4])

convenient pre-filled applicators

EZ-Squeeze applicator

Pet Specifix™ Applicator

Accu-Tip Dispenser

Unique applicator design [shape] helps prevent misapplication [on dogs]

Longer applicator tip for easy application to long-haired cats

One [tube][applicator] gives 28 days (1 month)(4 weeks) protection

Triple pack

Advanced (Year-round)(Flea Treatment) Care (Preventative)

From ZODIAC®, the originator of IGR technology

Contains [With] PRECOR® (vIGRen®), the first insect growth regulator for flea control

Plus IGR Kills Flea Eggs

This product contains an Insect Growth Regulator

Flea control for cats with (PRECOR®)(vIGRen®) Insect Growth Regulator (IGR)

Advanced (topical) flea egg treatment that's easy and convenient to use

Kills and prevents (flea) eggs from hatching for up to (28 days)(1 month)(4 weeks)

Kills (flea) eggs before they hatch

Prevents reinfestation for up to (1 month)(28 days)(4 weeks)

Kills (hatching) flea eggs for up to (1 month)(28 days)(4 weeks) to prevent reinfestation

Interrupts normal flea development

Stops the flea life cycle

Controls(Kills)(Lasts)(Works)(Protects)(Eliminates) for up to 28 days (1 month)(4 weeks)

(Convenient) No mess, (easy)(simple) to (use)(handle)(apply) disposable applicator

Apply to one spot for head to tail (total body) flea protection (control)

Apply to 1 spot - spreads over the cat's complete body (from head to tail) through the natural motion of the animal

Spreads naturally with cat's movement (skin and hair oils)

(Satisfaction guaranteed)(Money back guarantee)(Guaranteed to Work)

Decorative 'c' symbols arranged in a pattern on the right side of the page.

(FRONT PANEL)

ACTIVE INGREDIENT:

(S)-Methoprene (CAS # 65733-16-6) 3.6%

OTHER INGREDIENTS: 96.4%

Total 100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back panel for additional precautionary statements

EPA Reg. No. 2724-488

Net Contents: X number - 0.034 fl oz (1cc) applicators

ACCEPTED
JAN 22 2013

EPA Est. No.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

2724-488

() = ALTERNATE COPY

READ ENTIRE LABEL BEFORE USE.

USE ONLY ON CATS OR KITTENS OVER 2.5 LBS AND OVER 12 WEEKS OF AGE

(Specially formulated for cats) For use on cats only

INTRODUCTION:

RF 9804 (contains) is a topically applied [long-lasting] insect growth regulator (IGR)(product) specifically formulated for cats and kittens to prevent and control flea infestations (kill fleas before they hatch)(which prevents flea eggs from maturing into adults). Its active ingredient, S-Methoprene, an IGR prevents adult female fleas from laying viable eggs. A single application of RF 9804 will last for up to 28 days (1 month)(4 weeks). Each package contains enough product for (three or four)(3 or 4) monthly applications (90 or 120 days of protection). RF 9804 Topical provides relief from flea infestations for one month by controlling and preventing flea eggs on your cat and kitten. Adult fleas can live on your cat while producing vast numbers of eggs which drop off your cat and develop in the surrounding environment. Normal insecticides will not kill the flea eggs, but RF 9804 Topical (is designed to) kill(s) flea eggs, thereby breaking the flea life cycle.

After application, through its natural movement, your cat's skin and hair oils (disperse) carry RF 9804 Topical over the cat's body for protection against flea eggs. Once fleas are evident on your cat, there is already an infestation of their preadult stages in your home. To kill existing adult flea populations, you may need to treat the home, cat's bed, and yard with traditional flea products approved for use on cats, around the home, or in your yard (such as home sprays, foggers, and/or yard and kennel spray). RF 9804 Topical can be used in conjunction with the entire ZODIAC product line for cats. As with all flea products, they are (RF 9804 Topical is) most effective when used as part of a total program aimed at reducing fleas in the cat's environment. Be sure to treat the cat's bedding and surroundings with [Brand Name] flea and tick products registered for these uses, such as the ZODIAC® line.

(ZODIAC products are designed to complement each other in an integrated program for flea and tick management. To assure proper treatment, we recommend use of only ZODIAC products. For complete efficacy, treat all pets in the household.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product contains (three or four)(3 or 4) monthly doses (one monthly dose), each (1 cc).

DO NOT USE ON OTHER ANIMALS. Remove one applicator tube from package. Holding the applicator tube in an upright position, simply press cap down to break the seal of tube. (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades and squeeze out the (entire) contents of the tube onto the cat's skin. Repeat every month.

ALTERNATE PACKAGING DIRECTIONS (A)

Use ONLY on cats or kittens over 12 weeks of age. Do not apply to cats weighing less than 2.5 lbs. Do not allow your cat to ingest this product. [Bend at perforation and tear off 1st month's applicator.] Hold applicator and bend numbered area of plastic at perforation, tear off and discard. [Hold applicator upright away from face and body and use scissors to cut secure seal applicator tip.] Hold [applicator] upright and snap tip back, away from face and body. Prior to application of the product, gently lift the cat's (kitten's) haircoat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the (entire) contents of the [applicator] tube onto the cat's skin. Because of the bitter taste of the product, some cats may salivate if they are able to lick the product when grooming right after application. This effect is temporary and is not harmful. Repeat application once monthly. Do not use more than one applicator per cat and do not apply more than once every month.

ALTERNATE PACKAGING DIRECTIONS (B)

Use ONLY on cats or kittens over 12 weeks of age. Do not apply to cats weighing less than 2.5 lbs. Do not allow your cat to ingest this product. Remove one applicator tube from package and hold in an upright position. Simply twist (press) cap (down) to break the seal of tube. (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Prior to application of the product, gently lift the cat's (kitten's) haircoat on the back of the neck at the base of the skull, position the tip of the tube on the cat's exposed skin and squeeze out the (entire) contents of the tube onto the cat's skin. Because of the bitter taste of the product, some cats may salivate if they are able to lick the product when grooming right after application. This effect is temporary and is not harmful. Repeat application once monthly. Do not use more than one applicator per cat and do not apply more than once every month.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. **Storage:** Store in a cool, dry place. **Disposal: If Empty:** Do not reuse this container. Place in trash or offer for recycling if available. **If Partly Filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS - CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS - CAUTION: Do not use on kittens less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your cat/kitten with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Due to the bitter taste of the product, oral exposure could result in salivation. Be careful not to get any product in the cat's mouth during application. For multiple cat households, prevent the cats from grooming each other until the product has dried. If an oral exposure occurs, offer the cat a taste treat, such as tuna, milk, or any other food item your cat enjoys. If the problem continues or other clinical signs are noted, please call 1-800-number.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor immediately for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

(If not completely satisfied, return unused portion for a full refund.) Guaranteed to work or your money back. Be sure to read full directions and precautions on the label. In case of an emergency (help at any step), or for product use information, call (telephone number, time) or visit our Web Site:[URL].

SIDE EFFECTS: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Brand at 1-800-number]

Wellmark International
1501 East Woodfield Road 200W
Schaumburg, IL 60173
[URL]
Made in USA

ZODIAC®, Spot On®, Pet Specifix™, PRECOR® and vIGRen® Insect Growth Regulator are trademark(s) of Wellmark International.

Applicator:

Product Name

S-Methoprene 3.6%

KEEP OUT OF REACH OF CHILDREN

CAUTION

For use only on cats over 2.5 lbs & over 12 weeks of age

[READ DIRECTIONS BEFORE USING.] (Optional if space allows)

EPA Reg No. 2724-488

Net Contents: 0.034 fl oz (1cc)

[US Patent No. _____]

